

 **Agriculture
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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir:

Please find attached requested comments from the Province of Nova Scotia regarding the proposed regulations concerning the prior notice of imported food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

The opportunity to comment on the proposed regulations is appreciated.

Yours sincerely,



Gordon Balser
Minister

Attachement

02N-D278

C184

Province of Nova Scotia
Comments on USFDA Draft Regulations
Public Health Security and Bioterrorism Preparedness Act of 2002
(Docket No. 02N-0278)

Introduction

The Province of Nova Scotia shares concerns with longstanding U.S. seafood importers and other trade partners regarding the higher costs of sourcing Canadian supplies that will result from regulations under the Bioterrorism Act. Disruptions and delays to perishable high value shipments would be particularly costly and would reduce the quality of products provided to consumers. The following provides comments and suggestions on how the proposed regulations might be adjusted and modified to reduce the economic costs on both sides of the border. These have been developed with the intent of never sacrificing the effectiveness of security measures and in some cases meaningful improvements appear achievable. The importance of the security objectives of the Act are acknowledged and understood.

Direct Notification

Nova Scotia shipper-exporters normally serve as the US importer for custom purposes. Suppliers typically handle all arrangements including custom clearance and delivery to the customer's warehouse. Accordingly if they are able to directly make the advanced shipment notification themselves the notifications can be made earlier and the information submitted will be more accurate as compared with the situation if a third party must unnecessarily become involved. Consider the predictable errors which will arise to some degree when the very detailed information is entered electronically by a third party. There are thirteen (13) pieces of information required under the proposed regulations. Any errors in the notification can cause shipments to be held at the border. Such instances will be very serious and costly in the case of the seafood trade. This practical adjustment would improve and enhance security outcomes and better husband security resources. At the same time the change allows more efficient/lower cost border movements for the benefit of shippers, trade customers, processors and final consumers.

Pre - Notification Time

Fresh and live seafood orders are routinely received and delivery made within twenty four hours. As well orders are often altered by purchasers more than once prior to the departure of the shipment. These practices support U.S. buyers' just-in-time delivery preferences and their high quality requirements. On occasion seafood orders are taken and commitments made prior to boats landing their (partly undetermined) catch. Consequently there is a likelihood that many notifications will be made on a speculative basis or with very partial information actually known regarding the composition of the final shipment. The Canadian Seafood Industry is proposing that in the particular case of live and fresh perishable seafood shipments that prior notice be required by no less than four hours before the shipment arrives at the border and with no

provision for amendments. Such a provision allowing four or even six hour notification would similarly facilitate all live animal and fresh fruit and vegetable shipments. Shippers of non perishable food products including seafood are better able to readily comply with the proposed "before noon the day before" pre-notification rule with allowance for a one-time amendment up to two hours before arrival. In the case of non-perishable shipments the proposed system would work. Others are proposing a "two options" approach in which any shipper could select the one that best suits their business. Such flexibility for the individual shipper would address many of the practical and economic concerns seemingly without hampering security outcomes.

Other Suggestions

CTPAT (Added Contribution)

Shipments from plants that are CTPAT and/or CFIA registered might be reported as such when the shipment notifications are made. This would allow the USFDA opportunities to better direct resources. U.S. Customs now expedites such shipments and it seems likely that there will at a minimum be situations when the USFDA might choose to be selective in allocating inspections on this basis as well.

Multi-Plant Operations

Significant deadweight costs can be avoided if firms with more than one plant can register all of their facilities under one number for prior notice purposes. This reference could provide the FDA with the full information required for food security assurances. Such multi-plant operations frequently process identical products at different locations and increased inventory controls will otherwise be necessary for shipment notification reasons without improving food safety.

Border Resources

Regardless of how well designed the new regulations are these measures will to some degree harm the highly integrated North American economy. Adequate resources at the border are an essential means to dissipate the negative impact and ensure security outcomes. A related issue involves infrastructure and new technology needs at Maritime (New Brunswick - Maine) border crossings. We will raise these matters in other avenues and particularly to our federal authorities.

Country of Origin

The country of origin for product filleted in Canada but caught, headed and gutted by a foreign vessel will be that foreign nation under the originating country definition. This treatment is inconsistent with international trade practices. It is the last point of processing that is relevant for security purposes and we question whether collecting this information is useful and consistent with the intent that the regulations not be more trade restrictive than necessary to meet the objectives of the Bioterrorism Act.

Note on Economic Impacts

Delays in crossing the border or other impediments would have significant ramifications for the operations of a broad range of U.S. (and particularly Maine and Massachusetts) businesses engaged in seafood processing, distribution and high end marketing. As well the earnings of a broad swath of our province's economy would be hurt. The U.S. export market for Nova Scotia seafood and other food products is critically important for many coastal and rural communities and for the overall provincial economy. In 2002 food export shipments from Nova Scotia to U.S. markets returned \$950 million. High value fresh and live products account for over half of the province's U.S. food exports. Most export shipments from Nova Scotia are made by small or medium size businesses.

CONCLUSION

Modifications to the proposed regulations under the Bioterrorism Preparedness Act, made in the full light of current commercial practices and conditions, could reduce the pending burden and the costs of the new regime for the seafood trade and its customers. These also involve operational improvements which will better husband and direct security resources.